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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,323	12/20/2004	Masazumi Nishikawa	263192US0PCT	3573

22850 7590 05/14/2007

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1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
MERCIER, MELISSA S	
ART UNIT	**PAPER NUMBER**
1615	

NOTIFICATION DATE	DELIVERY MODE
05/14/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/517,323	NISHIKAWA ET AL.	
	Examiner	Art Unit	
	Melissa S. Mercier	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Change of Examiner

The examiner assigned to the instant application has changed. The new examiner is Melissa Mercier. Contact information is provided at the end of this Office Action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 20, 2007 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

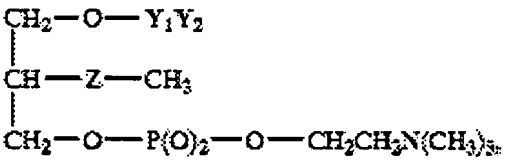
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-32 and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al. (US Patent 6,667,053).

Ahmed discloses a liposome having a lipid bi-layer, where the lipid bi-layer including either the L or D stereoisomer of an ether lipid. The liposome may be used as an anti-cancer agent (abstract). The ether lipid has the following formula:



wherein Y_1 is $(CH_2)_{n1}(CH{=}CH)_{n2}(CH_2)_{n3}(CH{=}CH)_{n4}(CH_2)_{n5}(CH{=}CH)_{n6}(CH_2)_{n7}(CH{=}CH)_{n8}(CH_2)_{n9}$. The sum of n1+2n2+n3+2n4+n5+2n6+n7+2n8+n9 is an integer of from 3 to 23, n1 is zero or an integer of from 1 to 22, n3 is zero or an integer of from 1 to 19, n5 is zero or an integer of from 1 to 16, n7 is zero or an integer of from zero to 16, n9 is zero or an integer of from 1 to 10, and each of n2, n4, n6 and 8 is independently zero or 1. Y_2 is CH_3 or CO_2H.

Z is oxygen or sulfur. Preferably, Z is O; accordingly, this invention's glycerol-based etherlipids preferably have a methoxy group at the sn-2 position of their glycerol backbone.

Also disclosed is a pharmaceutical composition comprising a pharmaceutically acceptable carrier and the liposome's, in additon to a method of treating a mammal

afflicted with a cancer, including carcinoma. The method comprises administering the compositions to the mammal, in an amount containing an anticancer effective amount of the ether lipid. Typically, the anticancer effective amount of the ether lipid is from about 0.1 mg of the ether lipid per kg of the body weight of the mammal to about 1000 mg per kg (column 3, lines 36-48). The method can also comprise administration of an additional bioactive agent, e.g., an antineoplastic agent, antimicrobial agent, therapeutic lipid or hematopoietic cell growth stimulating agent, to the mammal (column 3, lines 49-52).

The composition is further disclosed as comprising a pharmaceutically acceptable carrier, including dextrose, saline, preservatives, and antioxidants (column 10, lines 16-41).

Regarding the form of administration and dosing schedule, Ahmed discloses formulations for oral administration; it is the examiners position that one of ordinary skill in the art would possess the knowledge in order to prepare a variety of formulations including foods, emulsions, syrups, tablets, gums, and liquids. It is further the position of the examiner that one of ordinary skill in this art would have the knowledge for determining optimum dosing schedules of the composition in order to obtain the optimum therapeutic effect of the compound.

Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the

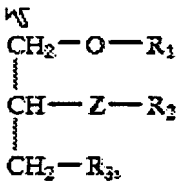
optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

It would have been obvious to a person of ordinary skill in the art to expand upon the teaching of Ahmed in order to prepare composition suitable for the treatment of skin damage, since Ahmed discloses the same compositions claimed to be used for the treatment of cancer including carcinoma and ether lipids are disclosed as being cytotoxic to cancer cells and have been shown to be effective anticancer agents, but generally non toxic to most normal cells (column 1, lines 57-68).

Since ethers are the active compounds, it is the examiners position that one of ordinary skill in the art would expect similar results irrespective of source, such as, shark liver oil recited in claim 23.

Claims 18-32, and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayhew et al. (US Patent 5,942,246).

Mayhew discloses liposome's which contain ether lipids having the formula:



Wherein, R1 of the ether lipid, the chain attached at the carbon #1 position of its glycerol backbone by way of an oxygen, has the formula Y1, Y2, Y2 is CH3 or CO2H; the sum of n1+2n2+n3+2n4+n5+2n6+n7+2n8+n9 is an integer of from 3 to 23; that is, the acyl chain is from 4-24 carbon atoms in length. n1 is equal to zero or is an integer of

from 1 to 23; n3 is equal to zero or is an integer of from 1 to 20; n5 is equal to zero or is an integer of from 1 to 17; n7 is equal to zero or is an integer of from 1 to 14; n9 is equal to zero or is an integer of from 1 to 11; and each of n2, n4, n6 and 8 is independently equal to zero or 1. The hydrocarbon chain is preferably saturated, that is, it preferably has no double bonds between adjacent carbon atoms, each of n2, n4, n6 and n8 then being equal to zero. Alternatively, the chain can have one or more double bonds, that is, it can be unsaturated, and one or more of n2, n4, n6 and n8 can be equal to 1.

Z is oxygen, sulfur, NH, or --NHC(O)--, Z then being connected to the methyl group by way of either the nitrogen or carbonyl carbon. Z can also be --OC(O)--, it then being connected to the methyl group by way of either the oxygen or carbonyl carbon atom.

R2 is an alkyl group, or a halogen-substituted alkyl group, having the formula (C(X1)n10 (X2)n11)n12 CX3 X4 X5, wherein each of X1, X2, X3, X4, and X5 is independently hydrogen or a halogen. n10 is equal to zero, 1 or 2; n11 is equal to zero, 1, or 2; and n12 is equal to zero or an integer of from 1 to 23 (column 3, line 65 through column 4, line 45).

The composition is further disclosed as comprising a pharmaceutically acceptable carrier, including dextrose, saline, preservatives, and antioxidants (column 8, lines 16-41).

Regarding the form of administration and dosing schedule, Ahmed discloses formulations for oral administration; it is the examiners position that one of ordinary skill

in the art would possess the knowledge in order to prepare a variety of formulations including foods, emulsions, syrups, tablets, gums, and liquids. It is further the position of the examiner that one of ordinary skill in this art would have the knowledge for determining optimum dosing schedules of the composition in order to obtain the optimum therapeutic effect of the compound.

Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

It would have been obvious to a person of ordinary skill in the art to expand upon the teaching of Mayhew in order to prepare composition suitable for the treatment of skin damage, since Mayhew discloses the same compositions claimed to be used for the treatment of cancer including carcinoma and ether lipids are disclosed as being cytotoxic to cancer cells and have been shown to be effective anticancer agents, but generally non toxic to most normal cells (column 1, lines 23-37).

Since ethers are the active compounds, it is the examiners position that one of ordinary skill in the art would expect similar results irrespective of source, such as, shark liver oil recited in claim 23.

Claims 18-38 rejected under 35 U.S.C. 103(a) as being unpatentable over Levin (US Patent 5,514,591), in view of Fuisz (US Patent 5,518,730).

Levin discloses the use of shark liver oil to be applied topically as an anti-wrinkle, anticancer, anti-inflammatory, agent (abstract). Applicant's disclosure on page 8 discloses a method for extracting diacylglyceryl ether from shark liver oil. Therefore, it is the examiners position that the use of shark liver oil would inherently possess the ether compound and thus the administration of shark liver oil would yield the same results.

Levin does not disclose the shark liver oil being orally administered.

Fuisz discloses the oral administration of shark liver oil. The composition may further comprise a variety of additives including excipients, lubricants, buffering agents, disintegrating agents, stabilizers, foaming agents, pigments, coloring agents, fillers, bulking agents, sweetening agents, flavoring agents, fragrances, release modifiers, adjuvants, plasticizers, flow accelerators, polyols, granulating agents, diluents, binders, buffers, absorbents, glidants, adhesives, antiadherents, acidulants, softeners, resins, demulcents, solvents, surfactants, emulsifiers, elastomers and mixtures thereof (column 10, lines 1-12).

Regarding the form of administration and dosing schedule, Ahmed discloses formulations for oral administration; it is the examiners position that one of ordinary skill in the art would possess the knowledge in order to prepare a variety of formulations including foods, emulsions, syrups, tablets, gums, and liquids. It is further the position of the examiner that one of ordinary skill in this art would have the knowledge for determining optimum dosing schedules of the composition in order to obtain the optimum therapeutic effect of the compound.

Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Levin with the dosage forms taught by Fuisz in order to obtain the convenience of administering a single dose of a medication (column 1, lines 10-12).

Conclusion

No claims are allowable. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MSMercier

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